Suggested Format for Residue Chemistry Study Reports

Storage Stability

OPPTS 860.1380

The purpose of this document is to suggest the format for final reports (right column) and to provide instructions for creation of Adobe PDF electronic submission documents (left column). The format is modeled after the NAFTA Data Evaluation Record template that will be used by OPP's and PMRA's scientists when this type of study is reviewed. The format is in outline form. The study report will include text and standard tables (detailed below).

Regarding PDF, both 'bookmarks' and 'links' are referenced. Bookmarks and links are similar in function in that both provide the reader with a way to move efficiently through a document as well as across documents. Bookmarks are a type of link that appear in the navigation pane on the left side of the PDF Reader user screen. Links appear within the body of a document as blue text. They permit the reader to jump to other locations with related information in the same document or other electronic documents. Tables should be imported into the PDF document from their native formats. See OPP's detailed technical specifications for creating PDF for details.

Residue Chemistry Study Reports – STORAGE STABILITY	
Instructions to create PDF	**Document Format**
Create Bookmarks for each item Document Format column.	• Study Title Page. • Statement of Data Confidentiality *No confidentiality claims can be made for electronically submitted studies at this time.* • GLP Statement. • QA Statement. • Table of Contents
Create links in summary to related text and tables in body of study report or appendices.	• Executive Summary. - Summary of Background Information & Experimental Design. - Summary of Results.
Create links to related tables.	• Background Information and Experimental Design. - Background Information – See Tables 1 and 2. - Experimental Design. - Analytical Methodology. • Results and Discussion – See Figure 1 and Tables 3 - 4.

Executive Summary:

Identify the crop/matrix tested and whether they were ground or whole. Indicate the chemical name, %ai, formulation type, spiking level, storage temperature, and duration. Show which residues (parent and/or metabolites) decreased and/or increased and by what percentage in each crop/matrix tested. Describe the method of analysis used to detect residues and whether this method was the same as that outlined in the analytical methodology. Indicate half-life if there is noticeable evidence of degradation. Indicate whether the data demonstrates that the test compound is stable and at what temperature, time duration, and in which crop/matrix.

Study/Waiver Acceptability/Deficiencies/Clarifications:

List any scientific deficiencies or clarifications that are needed.

Background Information

Give background information on the active ingredient, its mode of action, and the purpose of the end-use product.

Table 1 – Test Compound Nomenclature.

Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

Table 2 – Physicochemical Properties.

Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__°C)		
Solvent solubility (mg/L at __°C)		
Vapor pressure at __°C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log (K_{ow})		
UV/visible absorption spectrum		

Experimental Design:

Sample Preparation

Describe the spiking procedure, including the solvent used for the standard spiking solution, the concentration, the stability of this solution, the condition of the matrix at the time of spiking (e.g., extract, homogenate, macerate, etc.), the time allowed for equilibrium etc.

Analytical Methodology

If the analytical method is the same as the enforcement or data-gathering method, then reference the method and briefly describe the analytical method, instrumentation used in determining the residues, and the LOQ. Otherwise, provide a detailed method description.

Results and Discussion

Comment on the acceptability of the analytical method for determining residues in the storage stability study. Discuss the storage stability of the analyte(s) during the tested storage intervals. If there is noteworthy dissipation of the analytes, describe qualitatively and quantitatively (provide regression analysis if appropriate).

Figure 1. Include a graph of residue stability in matrix as applicable.

Table 3 – Summary of Concurrent Recoveries of [*chemical*] from [*matrix*].

Matrix	Analyte	Spike level (mg/kg)	Storage interval (days)	Sample size (n)	Recoveries (%)	Mean ± std.dev.

Table 4 – Stability of [chemical] Residues in [matrix] Following Storage at ___°C.

Commodity	Spike level (mg/kg)	Storage interval (days)	Recovered residues (mg/kg)	Corrected % recovery*

*Corrected for concurrent-recoveries